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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,208	02/01/2002	Wilson Burgess	CI-0026	7581

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,208	BURGESS ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *107,125-142,149-154,157-159,165,166 and 170-172* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *107,125-142,149-154,157-159,165,166 and 170-172* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The indicated allowability of claims 107 and 156 is withdrawn in view of the newly discovered reference(s) to Moore, Goertzen et al., and Livesey et al.. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (U.S. 5,645,851).

Moore teaches a method of sterilizing collagen wherein the collagen is irradiated. See col.3, lines 18-19 and lines 34-35. After the collagen has been irradiated it is placed into sterile containers and the turbidity of the collagen is examined. The lack of turbidity indicates a lack of microorganisms, meaning that the collagen has been sufficiently sterilized. See col.4, lines 30-35; col.5, lines 15-30. Although not specifically disclosed by Moore, it would follow that when the sample is turbid, it would have been obvious to further the irradiate the collagen in order to obtain the necessary level of sterility indicated by a lack of turbidity.

4. Claims 125-134, 140-142, 149, 166, and 170-172 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. ("Sterilisation of Canine Anterior Cruciate Allografts By Gamma Irradiation in Argon") in view of Livesey et al. (U.S. 5,336,616).

Goertzen et al. teaches a method of sterilizing bone-anterior cruciate ligament (ACL)-bone allografts with gamma radiation at a total dose of 2.5 Mrad (25 kGy). The allograft is deep-frozen to -80 °C ("about 78 °C") and maintained in an argon gas environment during irradiation. See Abstract; page 206, first full paragraph and last paragraph. Goertzen et al. does not disclose contacting the allografts with a stabilizer.

Livesey et al. discloses that when freezing a tissue, it is necessary to first contact the tissue with a stabilizer (cryoprotectant) in order to protect the tissue by reducing the rate of cooling and/or the freezing point and to reduce hypoxic damage to the tissue. See col.11, lines 55-60. Suitable cryoprotectants include DMSO (a penetration enhancer), propylene glycol, and polyhydric alcohols such as glycerol, sorbitol, and mannitol. See col.8, lines 1-10; col.11, line 49 to col.12, line 30; col.14, lines 36-54. The compositions illustrated in col.16, lines 30-50, all use propylene glycol at a concentration of 0.5 M in combination with DMSO at 0.5 M. VS1 and VS2 also include trehalose, a polyhydric alcohol. Livesey et al. further discloses that "[o]ptimum pH and buffering capacity against the products of hypoxia damage...is essential." See col.8, lines 67-68.

It would have been obvious to one of ordinary skill in the art to contact the ACL allografts of Goertzen et al. with the cryoprotectant composition of Livesey et al. because the grafts of Goertzen et al. are frozen before irradiation and because the cryoprotectants

of Levesey et al. are disclosed to be capable of preserving cell and tissue structure against injury associated with freezing.

5. Claims 135 and 150-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. in view of Livesey et al. as applied to claim 125 above, and further in view of Peterson (U.S. Patent No. 5,730,933).

With respect to claim 135, Goertzen et al. teaches maintaining the tissue in an inert (argon) atmosphere during irradiation but fails to teach vacuum. However, Peterson discloses doing both during irradiation of a tissue. See col.5, lines 28-35. As the removal of air from the environment (a vacuum) will reduce the presence of oxygen and thus, the production of damaging free radicals during irradiation just as in inert atmosphere does, it would have been obvious to do the same in the method of Goertzen et al. with Livesey et al..

As to claims 150-154, Goertzen et al. is silent with respect to lyophilizing the tissue before irradiation. Peterson teaches lyophilization of tissue before irradiation as a means by which to reduce the presence of free radicals due to water in the tissue. See col.5, lines 53-67. For this reason, it would have been obvious to lyophilize the tissue of Goertzen et al. before irradiation thereof and to remove the water to a desired level. When lyophilizing the tissue of Goertzen et al. that has been cryoprotected with the composition of Livesey et al. one would have intrinsically been removing a combination of naturally occurring aqueous solvents and organic solvents added during cryopreservation.

6. Claims 136-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. in view of Livesey et al. as applied to claim 125 above, and further in view of Salehpour et al. ("Dose-Dependent Response of Gamma Irradiation on Mechanical Properties and Related Biochemical Composition of Goat Bone-Patellar Tendon-Bone Allografts").

With respect to claim 136, the combination *supra* fails to disclose a rate at which to apply the gamma radiation. Salehpour et al. teaches that it was known in the art at the time of the invention to sterilize frozen bone-tissue allografts with radiation having a dose rate of 161.5 krad/hr (1.615 kGy/hr). See "Methods," second paragraph. As this dose rate has been shown to be both safe and effective in the sterilization of frozen tissues, it would have been an obvious dose rate to use in the combination of Goertzen et al. with Livesey et al..

As to claims 137-139, the dose employed by Goertzen et al. is 25 kGy. Salehpour et al., however evidences that a dose this low is insufficient to remove all HIV from the allografts and that in fact, doses higher than 30 kGy may be necessary. See page 898, second paragraph. Therefore, in order to assure complete destruction of all HIV and other pathogens in the allograft of Goertzen et al., it would have been obvious to irradiate the allograft at doses higher than 30 kGy, as determined by routine PCR testing.

7. Claims 157 and 158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. in view of Livesey et al. as applied to claim 125 above, and further in view of Horowitz et al. (U.S. Patent No. 5,712,086).

Goertzen et al. with Livesey et al. fail to disclose adding a sensitizer to the biological material before irradiation. Horowitz et al. teaches sterilizing biological

material wherein a sensitizer (purpurins, phthalocyanines, psoralens, etc.) may be added before irradiation. See col.6, line 64 to col.7, line 10. Horowitz et al. discloses that the use of a sensitizer achieves preferential damage to the virus, but not to the biological material. For this reason, it would have been obvious to add a sensitizer in the method of Goertzen et al. with Livesey et al..

8. Claim 165 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. in view of Livesey et al. as applied to claim 125 above, and further in view of Okrongly (U.S. Patent No. 5,283,034).

The combination *supra* fails to teach packaging the article before sterilization. Okrongly teaches the known packaging of an article to be sterilized by radiation. See col.5, line 60 to col.6, line 2. The packaging prevents the recontamination of the surface after sterilization. A step of packaging followed by terminal sterilization is well-known in the sterilization art and would have been obvious in the method of Goertzen et al. as a means by which to protect the sterilized allograft.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 126-141, 149-154, 157-159, 165, and 166 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 146-159, 161, 162, 164-168, 170-172, 175, and 176 of copending Application No. 10/133,631. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are fully encompassed by the claimed subject matter of claims of 10/133,631. In the claims of 10/133,631, "1,2-propanediol" corresponds to "propylene glycol" in the instant claims. Similarly, "DMSO" is the "penetration enhancer" of the instant claims and the remaining components include polyhydric alcohols.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (5:30 am-3:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
12 June 2006